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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,581

04/09/2004

Muraleedharan G. Nair

MSU 4.1-703

1970

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EXAMINER

LEITH, PATRICIA A

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,581	<b>Applicant(s)</b> NAIR, MURALEEDHARAN G.	
	<b>Examiner</b> Patricia Leith	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 2-6 and 9-13 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 12/13/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,423,365 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Rejections Removed***

The previous rejections made under 35 USC 112 Second paragraph are hereby removed due to Applicant's amendments to the claims in order to overcome those rejections.

### ***Specification***

The use of the trademark AMBERLITE XAD has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It does not appear that this trademark is accompanied by the generic terminology and therefore the Specification is objected to for this reason.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that Applicant's statements regarding the 'AMBERLITE' citations in the Specification were considered. However, while these citations are properly capitalized, they are not accompanied by generic terminology. Thus, the Specification remains in objection.

### ***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1655

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-6 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langston (US 4,500,556) in view of Mozaffar et al. (US 5817354 A) in view of Owades (US 4,233,334) and further in view of Wakat (US 6054128 A).

Claim 6 now recites:

(h) combining the mixture of (f) and (g) with a carrier for food use which consists essentially of berry pulp of the edible berry separated from the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice to produce a composition having antioxidant and anti-inflammatory activity.

Here, the limitation of 'consists essentially of' berry pulp' is a new limitation presented to the claims.

The teachings of Langston, Mozaffar et al. and Owades were discussed in the previous Office action. None of the references specifically taught combining the product obtained by Langston into a carrier which consisted essentially of pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice of the berry were removed.

Wakat (US 6054128 A) (see entire reference, especially excerpt specifically cited below) , disclosed that phenolics from grapes and other food sources were known antioxidants useful for protection of vascular cells from oxidant injuries:

The phytochemical component of the dietary supplements of the present invention may also include at least one of procyanidin or cyanidin and preferably, contains a mixture of procyanidin and cyanidin. These phytochemicals have antioxidant effect and have been demonstrated to protect vascular endothelial cells from oxidant injury. The procyanidin and cyanidin component of the present dietary supplement may be added as a mixture of both compounds or each may be added separately, in purified form or as an extract. In a preferred embodiment, procyanidin and cyanidin are added as a mixture and most preferably are obtained as an extract from grape seed or other plant containing sufficient amount of these compounds. The cyanidin-procyanidin component of the present dietary supplement is present in an amount of from about 5 mg to about 500 mg, preferably from about 7 mg to about 250 mg, and most preferably about 10 mg. Preferably the cyanidin-procyanidin mixture is obtained as a plant extract containing about 38 to about 40% cyanidin-procyanidin. In a most preferred embodiment of the invention, the dietary supplements contain a total amount of phytochemicals and bioflavonoids, including quercetin, catechin and procyanidin-cyanidin mixture in the range of from about 20 to about 50 mg, preferably from about 25 to about 40 mg and most preferably, about 30 mg (col. 5, line 50-col.6, line 6)

While it is true that the prior art did not explicitly teach a method for adding the extract as Instantly claimed into only a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice were removed to produce the composition, the differences between the claimed invention and that as suggested by the prior art are slight. It was already known in the art that phenolics such as anthocyanins from berries such as grapes were known to be colorants for food products, as well as antioxidants for use in medicinal purposes such as for treatment/prevention of cardiac disorders as disclosed by Wakat. While the prior art

Art Unit: 1655

does not specifically teach the addition of these phenolics into a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice are removed, the pulp as described by the claims was already known in the art to be a suitable carrier as taught by Mozzafar et al. Thus, it is deemed that the addition of the phenolics from a berry, such as grapes to known, conventional carriers would have been *a priori* obvious to one of ordinary skill in the art absent any unexpected result. Carriers known for pharmaceutical/neutraceutical compounding are abundant and well-known. it is not considered inventive to add a known medicinal product to an old carrier unless such a combination provides for an unexpected result.

Applicant's arguments were fully considered, but not found persuasive.

Applicant initially argues:

Langston describes the use of an aqueous extraction solvent containing HSO<sub>3</sub> ions for treating grape pomace to form an anthocyanin (HSO<sub>3</sub>) complex. The absorbent for the complex retains the HSO<sub>3</sub> ions. This is a completely different process than Applicant's process which does not use a chemical treatment of the anthocyanins (p. 9, Remarks).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "does not use chemical treatment") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

Art Unit: 1655

USPQ2d 1057 (Fed. Cir. 1993). It is noted that the method of the Instant claims states 'comprising' which is open language, allowing the incorporation of unspecified method steps or reacting agents/solvents. Thus, Applicant's arguments regarding the fact that Langston uses HSO<sub>3</sub> is not convincing. Further, it is clearly seen in the Langston patent that the very small amount of HSO<sub>3</sub> which is used in the chromatography step actually enhances the adsorption of phenolics to the column and does not effect the product obtained after elution, as the HSO<sub>3</sub> is not eluted with the phenolics.

With regard to Mozaffar et al., Applicant argues:

Mozaffar et al. relates to a process for absorbing bitterness compounds in citrus juices which are not "edible berries". This is much different than the claimed process in that the bitterness is an unwanted compound which is absorbed (p. 9, Remarks).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the Instant case, it is clear that Mozaffar et al. teach that blending fruit prior to extraction was well known, and hence the ordinary artisan would have recognized blending as an obvious routine step in the protocol to obtain an extract from fruit. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.



Art Unit: 1655

With regard to the Owades patent, Applicant argues:

Owades describe a process wherein cellulose pulp is beaten to provide a carrier. This reference has nothing to do with the claimed invention. Thus, the combination of references could not possibly produce the claimed invention from this combination of references without using hindsight. Reconsideration is requested (pp. 9-10, Remarks).

Again, Applicant is arguing the references individually, while the rejection is made in view of the combination of the references. It is deemed that the ordinary artisan, with the above-cited references before him/her would have had a reasonable expectation of success in producing phenolics from grapes, as the differences between the claimed invention, and that which is taught by the prior art is very minor. [If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.

Claims 2, 3, 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langston (US 4,500,556) in view of Mozaffar et al. (US 5817354 A) in view of Owades (US 4,233,334) in view of Woznicki et al. (US 4,336,244 A) in view of Wakat (US 6054128 A).

Claim 6 now reads:

Art Unit: 1655

(h) combining the mixture of (f) and (g) with a carrier for food use which consists essentially of berry pulp of the edible berry separated from the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice to produce a composition having antioxidant and anti-inflammatory activity.

Here, the limitation of 'consists essentially of' berry pulp' is a new limitation presented to the claims.

The teachings of Langston, Mozaffar et al. and Owades were discussed in the previous Office action. None of the references specifically taught combining the product obtained by Langston into a carrier which consisted essentially of pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice of the berry were removed.

Wakat (US 6054128 A) (see entire reference, especially excerpt specifically cited below) , disclosed that phenolics from grapes and other food sources were known antioxidants useful for protection of vascular cells from oxidant injuries:

The phytochemical component of the dietary supplements of the present invention may also include at least one of procyanidin or cyanidin and preferably, contains a mixture of procyanidin and cyanidin. These phytochemicals have antioxidant effect and have been demonstrated to protect vascular endothelial cells from oxidant injury. The procyanidin and cyanidin component of the present dietary supplement may be added as a mixture of both compounds or each may be added separately, in purified form or as an extract. In a preferred embodiment, procyanidin and cyanidin are added as a mixture and most preferably are obtained as an extract from grape seed or other plant containing sufficient amount of these compounds. The cyanidin-procyanidin component of the present dietary supplement is present in an amount of from about 5 mg to about 500 mg, preferably from about 7 mg to about 250 mg, and most preferably about 10 mg. Preferably the cyanidin-procyanidin mixture is

Art Unit: 1655

obtained as a plant extract containing about 38 to about 40% cyanidin-procyanidin. In a most preferred embodiment of the invention, the dietary supplements contain a total amount of phytochemicals and bioflavonoids, including quercetin, catechin and procyanidin-cyanidin mixture in the range of from about 20 to about 50 mg, preferably from about 25 to about 40 mg and most preferably, about 30 mg (col. 5, line 50-col.6, line 6)

While it is true that the prior art did not explicitly teach a method for adding the extract as Instantly claimed into only a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice were removed to produce the composition, the differences between the claimed invention and that as suggested by the prior art are slight. It was already known in the art that phenolics such as anthocyanins from berries such as grapes were known to be colorants for food products, as well as antioxidants for use in medicinal purposes such as for treatment/prevention of cardiac disorders as disclosed by Wakat. While the prior art does not specifically teach the addition of these phenolics into a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice are removed, the pulp as described by the claims was already known in the art to be a suitable carrier as taught by Mozzafar et al. Thus, it is deemed that the addition of the phenolics from a berry, such as grapes to known, conventional carriers would have been *a priori* obvious to one of ordinary skill in the art absent any unexpected result. Carriers known for pharmaceutical/neutraceutical compounding are abundant and well-known. it is not considered inventive to add a known medicinal product to an old carrier unless such a combination provides for an unexpected result.

Applicant's arguments were fully considered, but were not found convincing.

With regard to this rejection, the Applicant argues:

Woznicki et al. describes a coating which is a water insoluble natural dye and cellulose. There is no such coating in Applicant's compositions. Thus, the combination of references could not produce the claimed invention. Reconsideration is requested

Again, Applicant is arguing the references individually, while the rejection is made in view of the combination of the references. It is deemed that the ordinary artisan, with the above-cited references before him/her would have had a reasonable expectation of success in producing the claimed invention. While Woznicki et al. may teach additional additives to their tablet which are not specifically claimed, there is no proviso in the claim that the tablets do not contain a coating and thus does not exclude the Woznicki et al. reference. Woznicki et al. clearly teach that Woznicki et al. (US 4,336,244 A) taught colored tablets, wherein the coloring agents were derived from natural sources (such as anthocyanins) for use in food preparations and advantageously included cellulose as a carrier (see entire reference, especially the Abstract and claims 1-16). One of ordinary skill in the art would have been motivated to formulate the colored extract of Langston into tablets in order to readily store and manufacture colored tablets for use as food coloring agents. It is clear from Woznicki et al. that this concept is well-known and used in the art of food coloring. Because cellulose is present in the tablets as a binder, and pulp is primarily made of cellulose,

Art Unit: 1655

one of ordinary skill in the art would have been motivated to grind pulp of fruit such as grapes in order to add to a tablet as a binder.

Claims 2-6 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langston (US 4,500,556) in view of Mozaffar et al. (US 5817354 A) in view of Owades (US 4,233,334) in view of Woznicki et al. (US 4,336,244 A) in view of Leo et al. (US 2,749,243) and further in view of Wakat (US 6054128 A).

Claim 6 now recites:

(h) combining the mixture of (f) and (g) with a carrier for food use which consists essentially of berry pulp of the edible berry separated from the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice to produce a composition having antioxidant and anti-inflammatory activity.

Here, the limitation of 'consists essentially of' berry pulp' is a new limitation presented to the claims.

The teachings of Langston, Mozaffar et al. and Owades were discussed in the previous Office action. None of the references specifically taught combining the product obtained by Langston into a carrier which consisted essentially of pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice of the berry were removed.

Wakat (US 6054128 A) (see entire reference, especially excerpt specifically cited below) , disclosed that phenolics from grapes and other food sources were known antioxidants useful for protection of vascular cells from oxidant injuries:

The phytochemical component of the dietary supplements of the present invention may also include at least one of procyanidin or cyanidin and preferably, contains a mixture of procyanidin and cyanidin. These phytochemicals have antioxidant effect and have been demonstrated to protect vascular endothelial cells from oxidant injury. The procyanidin and cyanidin component of the present dietary supplement may be added as a mixture of both compounds or each may be added separately, in purified form or as an extract. In a preferred embodiment, procyanidin and cyanidin are added as a mixture and most preferably are obtained as an extract from grape seed or other plant containing sufficient amount of these compounds. The cyanidin-procyanidin component of the present dietary supplement is present in an amount of from about 5 mg to about 500 mg, preferably from about 7 mg to about 250 mg, and most preferably about 10 mg. Preferably the cyanidin-procyanidin mixture is obtained as a plant extract containing about 38 to about 40% cyanidin-procyanidin. In a most preferred embodiment of the invention, the dietary supplements contain a total amount of phytochemicals and bioflavonoids, including quercetin, catechin and procyanidin-cyanidin mixture in the range of from about 20 to about 50 mg, preferably from about 25 to about 40 mg and most preferably, about 30 mg (col. 5, line 50-col.6, line 6)

While it is true that the prior art did not explicitly teach a method for adding the extract as Instantly claimed into only a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice were removed to produce the composition, the differences between the claimed invention and that as suggested by the prior art are slight. It was already known in the art that phenolics such as anthocyanins from berries such as grapes were known to be colorants for food products, as well as antioxidants for use in medicinal purposes such as for treatment/prevention of cardiac disorders as disclosed by Wakat. While the prior art

Art Unit: 1655

does not specifically teach the addition of these phenolics into a pulp of a berry wherein the acids, sugars, anthocyanins, bioflavonoids and phenolics contained in the juice are removed, the pulp as described by the claims was already known in the art to be a suitable carrier as taught by Mozzafar et al. Thus, it is deemed that the addition of the phenolics from a berry, such as grapes to known, conventional carriers would have been *a priori* obvious to one of ordinary skill in the art absent any unexpected result. Carriers known for pharmaceutical/neutraceutical compounding are abundant and well-known. it is not considered inventive to add a known medicinal product to an old carrier unless such a combination provides for an unexpected result.

Applicant's arguments were fully considered, but not found convincing.

Applicant argues:

Claim 4 relates to quick freezing. This is merely a preferred embodiment. It is important that the anthocyanins be preserved. The method of making the food product is completely different from Applicant's invention. Reconsideration is requested

Again, Applicant is arguing the references individually, while the rejection is made in view of the combination of the references. It is deemed that the ordinary artisan, with the above-cited references before him/her would have had a reasonable expectation of success in producing the claimed invention because the use of quick-frozen berries was preferred for making juices because the use of quick-frozen berries retained the freshness of the berries prior to processing according to Leo et al.

Thus, while Applicant argues that each individual reference combined with the Langston patent provides for various methods for producing foodstuffs, the references none-the-less teach the minor modifications in the claimed invention which were not found in Langston. It is deemed that these modifications would have been routine, and well within the realm of the ordinary artisan's expertise. The Office has provided references which teach the limitations of the claimed invention, and further provided motivation for why one of ordinary skill in the art would be advantageously inclined to make such modifications. In this sense, the rejection remains obvious over the combination of references.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



Art Unit: 1655

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
Art Unit 1655

/Patricia Leith/  
Primary Examiner, Art Unit 1655